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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/700,813 | 03/14/2001 | Rocio M. Sierra-Honigmann | 044574-5029- | 4201 |

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EXAMINER

CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,813

Applicant(s)

SIERRA-HONIGMANN, ROCIO M.

Examiner

Gyan Chandra

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/01/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 7, claims 18-20, in the reply filed on 1/11/2006 is acknowledged. The traversal is on the ground(s) that there is an error in listing of generic claims for Group 1 and states that in addition to claim 1, claims 2 and 5-7 are generic as well. This is found persuasive. Therefore, the species election of Group 1 would read on generic claims 1-2, and 5-7.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1-17 and 21-28 are canceled.

Claims 18-20 are pending and under examination.

Information Disclosure Statement

The information disclosure statement filed 5/01/02 has been considered.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Snodgrass et al. (U.S. Patent No. 6,355,237).

The claims are drawn to a method for (i) promoting the formation, maintenance or repair of tissue comprising administering, a subject in need of, an effective amount of

Art Unit: 1646

an agent that induces a leptin or leptin receptor mediated angiogenic response in the subject, (ii) wherein the angiogenic response affects vascular cells in the subject, and (iii) wherein the agent is administered locally and the vascular cell response occurs locally.

Snodgrass et al teach that leptin is known as OB protein which activates hematopoietic and endothelial lineages in vivo or ex vivo, and when used in vivo in patients with immunodeficiency and anemia, leptin promotes angiogenesis and vasculogenesis (column 4, lines 22- 27, column 17, 30-38). Snodgrass et al teach that leptin can be administered to a patient in various therapeutic doses that would be sufficient to ameliorate or treat various disorders and deficiencies and further suggest to deliver leptin therapeutic dosage as per need such as intravenous, subcutaneous, parenteral and intramuscular. They suggest that delivery can be designed to achieve maximum effect with minimum side effects; this includes use of various method of preparation with excipients and local delivery including implants (columns 18-20 and Example 8). Therefore, a local or systemic delivery can achieve its response in local vascular tissues or in a systemic manner, and since the skill of the art is high, a delivery system can be designed to deliver a drug to achieve its targeted effect.

Conclusion

No Claim is allowed.

Pertinent References:

1. U.S. Patent No. 5,879,713. Teaches targeted delivery of pharmaceutical compositions.
2. U.S. Patent No. 6,203,991. Teaches targeted delivery of pharmaceutical compositions.
3. U.S. Patent No. 6,290,949. Teaches targeted delivery of pharmaceutical compositions.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**EILEEN B. O'HARA
PRIMARY EXAMINER**

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Art Unit 1646
28 March 2006
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